

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

V.

2:16 MD 1203

8520

August 30, 2010

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify for compensation purposes Diet Drug Recipients based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also

(continued...)

To seek Matrix Benefits, a representative claimant<sup>3</sup> must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In or around May, 2006, Douglas E. McDonald, Administrator of the Estate, submitted a completed Green Form to the Trust signed by the attesting physician, Manoj Muttreja, M.D. Based on an echocardiogram dated December 12, 2002, Dr. Muttreja attested in Part II of the Green Form that Gail M. McDonald ("Ms. McDonald") suffered from moderate mitral regurgitation, an

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2. (...continued)  
may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of \$1,144,966.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Dr. Robert Rosenthal, measured Ms. McDonald's mitral regurgitation at 28%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In December, 2006, the Trust forwarded the claim for review by Michelle Penkala, M.D., one of its auditing

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4. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V benefits if the Diet Drug Recipient qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). As the Trust does not contest the presence of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise, the Estate must only establish that Ms. McDonald qualified for Level II benefits. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.c.(2)(b). An abnormal left atrial dimension and an ejection fraction less than or equal to 60% are each complicating factors. See id. §§ IV.B.2.c.(2)(b)ii)& iv). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, the only issue is claimant's level of mitral regurgitation.

cardiologists.<sup>5</sup> In audit, Dr. Penkala concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because Ms. McDonald's echocardiogram demonstrated physiologic mitral regurgitation.<sup>6</sup> In support of this conclusion, Dr. Penkala explained that:

[T]he color gain is excessively high with speckling seen although the Nyquist limit is acceptable. The traced putative [mitral regurgitant] jet is seen only in early systole and extends to the [left ventricle] side of the valve. This appears to represent only classic backflow. There is no significant [mitral regurgitation] seen during the midportion or latter part of systole.

Based on the auditing cardiologist's finding that Ms. McDonald had physiologic mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.<sup>7</sup> In

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5. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that the Estate had a Matrix A-1, Level V claim, pursuant to the PPP, the Trust audited the Estate's claim.

6. The Report Of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue defines physiologic mitral regurgitation as "Non-sustained jet immediately (within 1cm) behind the annular plane or <+ 5% RJA/LAA."

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit (continued...)

contest, the Estate submitted a report from Dr. Muttreja, who declared, in pertinent part, that:

4. The color gain setting is not found on the videotape, and speckling might be caused by any number of factors, including obesity.

5. In this case, the patient's regurgitant jets are so far into the moderate range that the color gain setting could have no effect on these images. Most importantly, as stated by the Auditing Cardiologist, the Nyquist limit was acceptable, and therefore, I found no false color images assigned to the regurgitant jets.

6. I manually retraced the regurgitant jets that are found on the videotape dated 12/12/02. I found a RJA/LAA ratio equal to or greater than 20% at what appears to be the following marks found on the videotape: 19:11.18, 18:13.09, 17:32.18, 10:20.29, 10:01.04, 9:44.15, and 9:43.23[.]

7. I appropriately found these regurgitant jets in early-systole. I saw these regurgitant jets in relation to the QRS complex that was obtained simultaneously with the occurrence of these jets. As the left ventricle fully contracted, the mitral valve was closed. The jets were not backflow. The jets extended into the left atrium, and they did not extend to the left ventricle side of the mitral valve.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Thereafter, Dr. Penkala provided a declaration wherein she confirmed her findings at audit; namely, that there was no reasonable medical basis for Dr. Muttreja's finding of moderate

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7. (...continued)

Rules contained in PTO No. 2807 apply to the Estate's claim.

mitral regurgitation on Ms. McDonald's echocardiogram.

Specifically, Dr. Penkala stated:

8. ... I again reviewed the entirety of Claimant's December 2, 2002<sup>8</sup> echocardiogram tape, as well as Claimant's Contest Materials.

\* \* \*

12. I specifically reviewed Claimant's echocardiogram tape at the following marks: 19:11.18; 18:13.09; 17:32.18; 10:20.29; 10:01.04, 9:44.15; and 9:43.23. Each of the putative 'jets' of mitral regurgitation depicted in these segments occurs during the very earliest part of systole, on or about the QRS complex. The CW Doppler confirms regurgitant flow in only the earliest part of systole; on frame-by-frame analysis this is only 1-2 frames in duration and thus consistent with backflow, not true mitral regurgitation.

13. I once again noted the prominent speckling of color seen at the beginning portion of the tape. Here, speckling is seen over the myocardium, suggestive of excessive color Gain. The speckling demonstrated here is not the result of obesity.

The Trust then issued a final post-audit determination, again denying the claim. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On July 13, 2007, we issued an Order to show cause and referred the

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8. Dr. Penkala identified the date of Ms. McDonald's echocardiogram as December 2, 2002 rather than December 12, 2002.

matter to the Special Master for further proceedings. See PTO No. 7313 (July 13, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on October 19, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that Ms. McDonald had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate reasserts the arguments made in contest. In addition, the Estate submits that Dr. Penkala did not disagree with Dr. Muttreja's determination that Ms. McDonald's RJA/LAA ratio "was equal to or greater than 20%." Instead, according to the Estate, Dr. Penkala determined the regurgitant jets were backflow. The Estate also notes that Dr. Penkala's conclusions are inconsistent with the findings of the Seventh Amendment cardiologist,<sup>10</sup> who determined Ms. McDonald's RJA/LAA was "21.4254799692%." Finally, the Estate argues that there is a reasonable medical basis for Dr. Muttreja's finding of moderate mitral regurgitation because "the Settlement Agreement associates left atrial enlargement with at least moderate mitral regurgitation."

In response, the Trust argues that Dr. Muttreja's declaration fails to provide a reasonable medical basis for his

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10. Claims subject to the Seventh Amendment were submitted to a Qualified Cardiology Center to determine whether the relevant echocardiogram demonstrated certain medical conditions, including mitral regurgitation. See Seventh Amendment to the Nationwide Class Action Settlement Agreement with American Home Products Corporation § XV.M.



finding of moderate mitral regurgitation. Specifically, the Trust contends that Dr. Muttreja "relied upon inappropriate echocardiogram settings and measurements of non-regurgitant flow ...." In addition, the Trust submits that Dr. Muttreja failed to observe Ms. McDonald's regurgitant jet throughout a portion of systole. Finally, the Trust asserts that the findings of the Seventh Amendment cardiologist are irrelevant to this proceeding.

The Technical Advisor, Dr. Abramson, reviewed Ms. McDonald's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. Specifically, Dr. Abramson stated in her report that:

The transthoracic echocardiogram from 12/12/02 is of suboptimal image quality. The parasternal views are very difficult to assess. In the apical views, there are many cardiac cycles (>250) with color flow imaging delineating the mitral regurgitation. Most of them demonstrate only mild [mitral regurgitation], but many of the cycles reveal a larger representative regurgitant jet consistent with moderate [mitral regurgitation]. Although some of the measured [mitral regurgitant] jets are over traced, and others contain non-regurgitant flow, most of the RJAs which are moderate in size, are traced accurately, are not in the earliest part of systole and are not backflow. My overall visual estimate is that there is mild to moderate mitral regurgitation with several representative jets demonstrating moderate mitral regurgitation.

Dr. Penkala states that the early systolic timing of the [mitral regurgitation], flow consistent with

backflow, and excessive color gain support her finding of physiologic regurgitation. Some of the cardiac cycles demonstrate mild mitral regurgitation with early systolic flow and some of them demonstrate backflow. But most of the representative cardiac cycles show a RJA/LAA >20% consistent with moderate mitral regurgitation. The color gain settings are appropriate in this obese patient with difficult images.

In summary, it is not unreasonable for the Attesting Physician's claim that this Claimant has moderate mitral regurgitation. Therefore, there is a reasonable medical basis to state that Gail McDonald has moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find that the Estate has established a reasonable medical basis for its claim. The attesting physician, Dr. Muttreja, reviewed Ms. McDonald's echocardiogram and found that she had moderate mitral regurgitation. Although the Trust challenged the attesting physician's finding, Dr. Abramson confirmed Dr. Muttreja's finding of moderate mitral regurgitation. Dr. Abramson determined that "most of the representative cardiac cycles show a RJA/LAA >20% consistent with moderate mitral regurgitation." Dr. Abramson also concluded that "most of the RJAs which are moderate in size, are traced accurately, are not in the earliest part of systole and are not backflow." Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement

Agreement § I.22. Here, Dr. Muttreja and Dr. Abramson found that the RJA/LAA ratio was greater than 20%. Under these circumstances, the Estate has met its burden to establish a reasonable medical basis for Dr. Muttreja's Green Form representation that Ms. McDonald had moderate mitral regurgitation.

For the foregoing reasons, we conclude that the Estate has met its burden of proving that there is a reasonable medical basis for its claim and is consequently entitled to Matrix A-1, Level V benefits. Therefore, we will reverse the Trust's denial of the Estate's claim for Matrix Benefits.